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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,721	02/12/2001	H. Michael Shepard	126745200402	5394

22836 7590 12/04/2001

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CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/04/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,721	Applicant(s) Shepard et al.
	Examiner L. E. Crane	Group Art Unit 1623

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3-- MONTH(S)** FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- Responsive to communication(s) filed on **-02/12/01 (IDS & amdt A) & 06/11/01 (Supp. IDS)**.
 This action is **FINAL**.
 Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claims **-1 & 56-89-** are pending in the application. Claims **-2-55-** have been cancelled.
 Of the above claim(s) **-1-** is/are withdrawn from consideration.
 Claim(s) **-1-** is/are allowed.
 Claims **-1 and 56-89-** are rejected.
 Claim(s) **-1-** is/are objected to.
 Claim(s) **-1-** are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawings, filed on **-05/15/01-** are approved disapproved.
- The drawing(s) filed on **-1-** is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
 All Some * None of the CERTIFIED copies of the priority documents have been received.
 received in Application No. (Series Code/Serial Number) **-1-**:
 received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-1-**.

Attachment(s)

- | | |
|--|---|
| <input checked="" type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). <u>--06--</u> | <input type="checkbox"/> Interview Summary, PTO-413 |
| <input checked="" type="checkbox"/> Notice of Reference(s) Cited, PTO-892 | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948 | <input type="checkbox"/> Other: <u>-1-</u> |

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The application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §1.821 through §1.825 for
5 the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given 3 (THREE) MONTHS from the date of this letter within which to comply with the sequence rules, 37 C.F.R. §1.821 -
10 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. §1.821(g). Extension of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. §1.136. In no case may an applicant extend the period for response beyond the SIX MONTH
15 statutory period. Applicant is requested to return a copy of the attached Notice To Comply with the response.

Applicant is referred to page 68 of the disclosure and the oligonucleotide sequences disclosed therein.

Claims 2-55 have been cancelled, no claims have been amended,
20 and new claims 56-89 have been added as per the preliminary amendment filed February 12, 2001. A submission including numerous completed Information Disclosure Statements (IDS's) filed February 12, 2001 has been received. Because the IDS's received including both PTO-1449's and PTO-892's specify other case serial numbers and are signed and dated, it is not possible for examiner to complete same. Examiner respectfully requests PTO-1449 forms which list references not already 25 of record, which specify the instant case serial number, and are not

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signed or dated. A supplemental Information Disclosure Statement (IDS) filed June 11, 2001 has been received with no cited references and made of record. Applicant is referred to the PTO-892 wherein all documents cited on the supplemental IDS have been made of record.

5 **Claims 1 and 56-89** remain in the case.

Claims **1 and 85** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims **1 and 85** reference is made to assays using compounds which have been disclosed generically or subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been tested.

15 Claims **56-61, 84 and 86-89** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 In claims **56-61, 81-84 and 86-89** reference is made to methods of treatment using compounds which have been disclosed generically or subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been tested and as to the types of cancer which can be treated; no data is provided to show effective treatment of liver cancer.

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Claims 62-89 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of
5 the claimed invention.

In claims 62-89 reference is made to compounds which have been claimed generically and subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been actually synthesized.

10 Claims 1 and 56-59, 61-63, 65, 72 and 81-87 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 In claim 57 at line 1, the term "characterized by" is indefinite because the meaning implied by the noted term is not judicially established. Additionally the following term "hyperproliferative cells" are indefinite for failure to specify the particular disease being referred to; is it cancer and if so which cancer or cancers? Or alternatively, is the disease some variety of psoriasis? See also claims 56, 58, 81-84, 86
20 ("pathological cell" fails to define the disease) and 87.

25 In claim 58 the terms "a sugar substituent," "a thio sugar substituent," a carbasugar substituent," and "a seco-sugar substituent"(SP){substituent} are indefinite for failure to provide the structural details to the chemical species being referred to. In particular the term "seco-sugar" is entirely lacking in any structural meaning to instant examiner.

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In claim 59 the term "masked phosphoryl moiety and a phosphoramidatyl moiety" needs the underlined term added (Markush group otherwise incomplete) and is indefinite for failure to provide the structural details to the chemical species being referred to.

5 In claim 61 at lines 3, the terms "alkene" and "alkyne" are compound names whereas -- alkenyl -- and -- alkynyl -- are the correct terms for derived substituents. Additionally beginning at the end of line 4, the particular groups being referred to is confused (missing punctuation?) and requires clarification. -- cyano -- is
10 -- -CN --, thiocyanate is the ion -- SCN⁽⁻⁾ -- (did applicant intend the substituent-- thiocyanato --?), cyanide is CN⁽⁻⁾ ion (not properly part of this list), and the term "thiocyanate halovinyl" is unclear as to the intended structural meaning (missing punctuation?).

15 In claim 62 at lines 10-11, the term "aromatic hydrocarbyl group" does not consist of "one or more unsaturated hydrocarbyl groups," although this may appear to be the case. Similarly at lines 11-12 a heteroaromatic group (2-, 3-, or 4-pyridinyl radical?) is not correctly defined as consisting of "one or more unsaturated hydrocarbyl groups," wherein no heteroatoms are provided for. Examiner would find it easiest
20 to discuss how this problem may be addressed effectively if applicant's representative would arrange a telephonic interview.

In claim 62 at line 27, the line needs to have the term -- and -- added at the end to make the Markush group proper.

25 In claim 62 at lines 41 and 42, the terms " -anomeric" is incomplete. (alpha and beta?).

Claims 63, 65, 72 and 85 appear to lack terminal punctuation.

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The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims 56-61, 81-84 and 86-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-12 of copending Application No. 09/130,839. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim **62-80** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **36-39** of copending Application No. **09/235,961**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **56-84** and **86-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-7** of U. S. Patent No. **6,245,750**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

Claims **1, 56-84** and **86-89** of this application conflict with claims of Application Nos. **09/130,839** and **09/235,961**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 5 §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

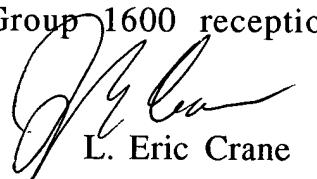
10 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

25 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

LECrane:lec
12/03/01



L. Eric Crane
Patent Examiner
Group 1600